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# Children's Susceptibility to Carcinogens Using Benzo[a]pyrene Example Chemical

MTCA/SMS Advisory Group  
March 22, 2010

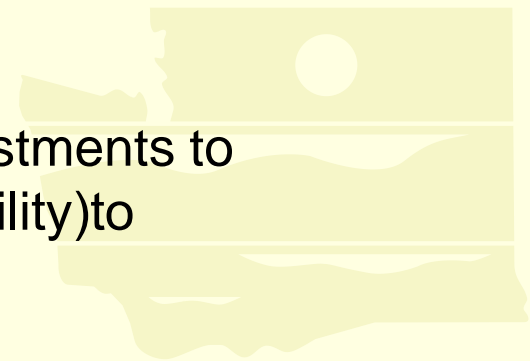
# Should Ecology update the MTCA rule to better protect children?

- Scientific evidence:
  - New information on toxicity
  - New information on childhood susceptibility
- New federal & state regulatory guidance & policies
- Ecology acknowledges uncertainty and variability in child susceptibility and exposures

**What else** should be considered as we incorporate adjustments based on children's increased susceptibility to carcinogens?

# Brief Background

- Ecology's policies and procedures to establish soil cleanup levels in WAC 173-340-740.
- MTCA methods based on EPA Risk Assessment Guidance for Superfund published in 1989.
- Technical information & recently published EPA & state regulatory guidance for life-stage approach to risk assessment that supersedes the 1989 guidance.
- Currently under MTCA there are no explicit adjustments to account for early-life exposure (child's susceptibility) to carcinogens.



# Standard MTCA Method B

## Soil Cleanup Equation (Equation 740-2)

(Soil MTCA Method B, Equation 740-2)

Soil Cleanup Level (mg/kg)	=	$\frac{\text{Risk} * \text{AT} * \text{ABW} * \text{UCF1}}{\text{CPFo} * \text{AB1} * \text{EF} * \text{ED} * \text{SIR}}$ <p>(Ingestion Component)</p>
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### Where:

Risk = Acceptable cancer risk level ( $10^{-6}$ )

ABW = Average body weight over the exposure duration (16 kg)

AT = Averaging time (75 years)

UCF = Unit conversion factor ( $10^6$  mg/kg)

CPF = Carcinogenic potency factor(kg-day/mg)

SIR = Soil ingestion rate (200 mg/day)

AB1 = Gastrointestinal absorption fraction (1.0, unitless)

ED = Exposure duration (6 years)

EF = Exposure frequency (1.0, unitless)



# Modified MTCA Method B

## Soil Cleanup Equation (Equation 740-5)

(Soil Modified MTCA Method B, Equation 740-5)

Soil Cleanup Level (mg/kg)	=	$\frac{\text{Risk} * \text{AT} * \text{ABW} * \text{UCF1}}{\text{CPFo} * \text{AB1} * \text{EF} * \text{ED} * \text{SIR}}$	+	$\frac{\text{Risk} * \text{AT} * \text{ABW} * \text{UCF1}}{\text{CPFd} * \text{ABSd} * \text{EF} * \text{ED} * \text{SA} * \text{AF}}$
		(Ingestion Component)		(Dermal Component)

Where (Selected Exp. Parameters):

Risk = Acceptable cancer risk level ( $10^{-6}$ )

ABW = Average body weight over the exposure duration (16 kg)

AT = Averaging time (75 years)

UCF = Unit conversion factor ( $10^6$  mg/kg)

CPF = Carcinogenic potency factor(kg-day/mg)

SIR = Soil ingestion rate (200 mg/day)

AB1 = Gastrointestinal absorption fraction (1.0, unitless)

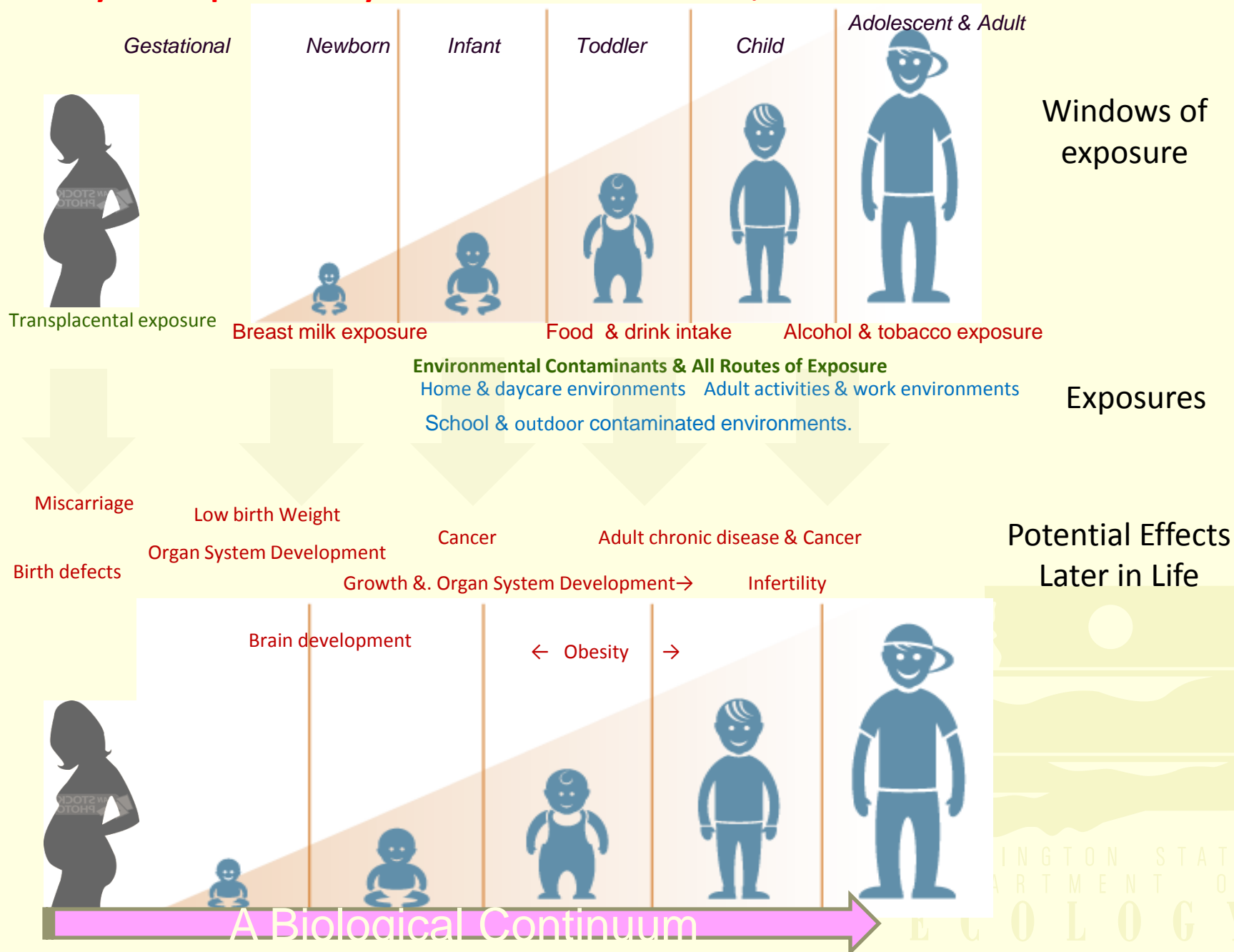
ED = Exposure duration (6 years)

EF = Exposure frequency (1.0, unitless)

Dermal specific exposure parameters, SA & AF



# Early-Life Exposure May Create Effects Later in Life, or Even Future Generations



# Important Elements of Children's Exposure

- Surrounded by large & increasing number of chemicals
- Children are more heavily exposed and more vulnerable to many environmental chemicals than adults
- Children are **NOT** little adults
  - Greater exposure pound for pound
  - Diminished ability to detoxify and excrete
  - Increased biological vulnerability
  - More years of future life



# Life-Stage Approach to Risk Assessment

- Based on Temporal life-stages have distinct characteristics

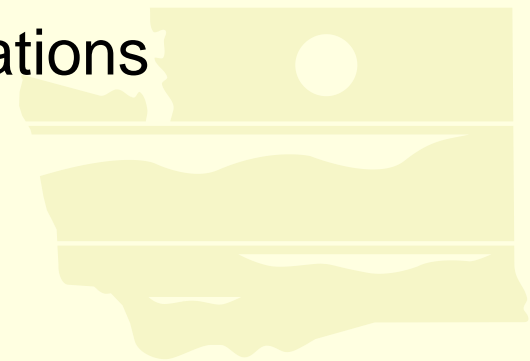
- Anatomical
- Physiological
- Behavioral
- Functional





# Consideration of Early-Life Exposures into the Risk Regulatory Paradigm

- Children represent 30% of U.S. population
- Not just a “special subpopulation” but are current inhabitants undergoing a vulnerable developmental stages which all human pass through
- Protection of children is essential
  - Prevention of disease in adults
  - Sustainability of healthy future generations
- Children are our future

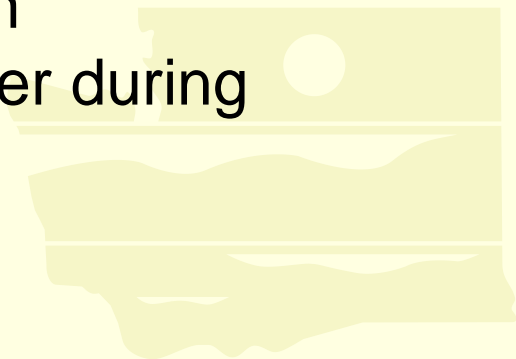


# Life-Stage Approach to Risk Assessment

- Consideration of:
  - Mode of Action of Chemical Contaminant
  - Critical Window of Sensitivity
  - Immediate and later- in- life effects
- Implication: life-stage approach to evaluate the toxicity and assess the risks from environmental exposures to carcinogens considers exposures as a continuum from childhood to adulthood

# State / Federal Regulatory Policies & Procedures To Reflect Children's Susceptibility to Carcinogens

- Proposed to update MTCA to reflect advances in technical information & regulatory guidance (late 1980's, early '90's) to account for children's susceptibility from exposure to carcinogens
- U.S. EPA Regions 3, 6, & 9; ORNL; NTP
- Other states: 50% are considering explicit guidance to account for children's susceptibility, two in implementation process, others to consider during next rule revisions



# Early-Life Exposure Adjustments

Early-Life Exposure (ELE) Age Adjustment Factors For Carcinogens, Soil Ingestion Pathway									
Parameter	Definition	Default Exposure Parameters For Early-Life Exposure							
		← Age Groupings →							
		< 2 years		2 to < 6 Years		6 to < 16 Years		Adult	
		Default	Alternative	Default	Alternative	Default	Alternative	Default	Alternative
ADAF	Age-Dependent Adjustment Factor, Unitless	10	----	3	----	3	----	1	----
ED	Exposure Duration, Years	2	----	4	----	10	----	14	----
BW	Body Weight, kg	16	10	16		70	45	70	----
SIR	Soil Ingestion Rate, mg/day	200	----	200	----	50	100	50	100
AF	Soil Adherence Factor, mg/cm <sup>2</sup> -event	0.2	----	0.2	----	0.2	----	0.2	0.07
SA	Body Surface Area Exposed, cm <sup>2</sup>	2200	2000	2200	3100	2500	5400	2500	5700

# Why Benzo[a]pyrene ?

- Why focus on benzo[a]pyrene to talk about today – because:
  - Consistent with federal/state regulatory guidance
  - Straightforward change for early-life exposure
  - Good example of factors under consideration in making risk management decision based informed science, policy, and MTCA regulatory framework



# Soil Cleanup Levels That Reflect Children's Susceptibility

## Example: B[a]P

Comparison of Soil Cleanup Levels for Carcinogens With & Without ELE Age Adjustments						
Chemical	Soil Cleanup Level Carcinogen Method B, Eqn.740-2 mg/kg	Soil Cleanup Level Carcinogen Method B, Eqn.740-5 mg/kg	Soil Cleanup Level Carcinogen ELE Dermal + Ingest. mg/kg		Soil Cleanup Level Carcinogen ELE Dermal + Ing + Inh mg/kg	
			Current	Alternative	Current	Alternative
Benzo[a]pyrene	1.37E-01	1.04E-01	1.70E-02	1.10E-02	1.70E-02	1.1E-02
Other States B[a]P Risk-Based Cleanup Level Range for ELE: $\approx 1.5\text{E-}02$ to $2.6\text{E-}01$ mg/kg EPA Region 3, 6, & 9 Residential Soil Screening Level for B[a]P = $1.5\text{E-}02$ mg/kg						

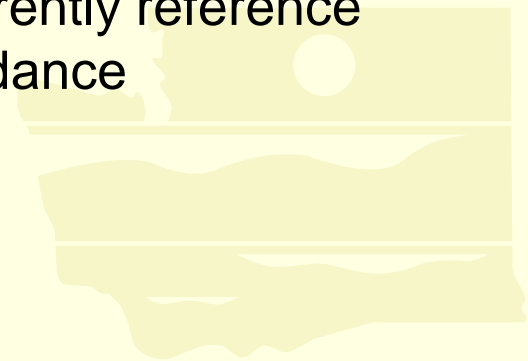
Comparison of ELE Cleanup Levels With Other Soil Values for B[a]P			
Carc. Soil Cleanup Level Dermal + Ingestion Method B, Eqn.740-5 mg/kg	Soil Cleanup Level Carcinogen ELE Dermal + Ingestion mg/kg	Soil Concentration Protective of GW 3-Phase Model mg/kg	Soil Background Concentrations mg/kg
1.04E-01	1.70E-02	4.3E-01	3.3 – Upper 95 %ile B[a]P-TEF 12.4 – Total c-PAHs 24 – Total PAHs $\approx 2.0$ – MyEIM 95% UCL 1.8 – Mean MyEIM

# Implications For MTCA Cleanup Regulation

## Update to

### Reflect Children's Susceptibility to Carcinogens

- Shift from risk-based decisions to consideration of background-based requirements, area-wide situations, and PQL's
- Cleanup levels for some or all carcinogens may be lower than under current rule when considering early-life exposure
- Consideration of concurrent exposure model as the standard model for risk-based calculations
- Update definitions and methodologies which currently reference late 1980's and early 1990's EPA regulatory guidance



# What Other Factors Should Ecology Consider?

- Given Ecology's consideration of:
  - Informed Science – Science Panel – Scientific Defensibility
  - Other State/Federal Regulatory Policies & Procedures
  - Comparison of different regulatory levels & potential impact & implication of considering children's susceptibility to carcinogens
  - Ecology is considering to revise the MTCA Cleanup Regulation to account for children's susceptibility from exposures to carcinogens
- Ecology will conduct a cost/benefit analysis as part of this revision, so what other factors should Ecology consider to revise MTCA to account for children's susceptibility to carcinogens?





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# Miscellaneous slides

- Miscellaneous slides

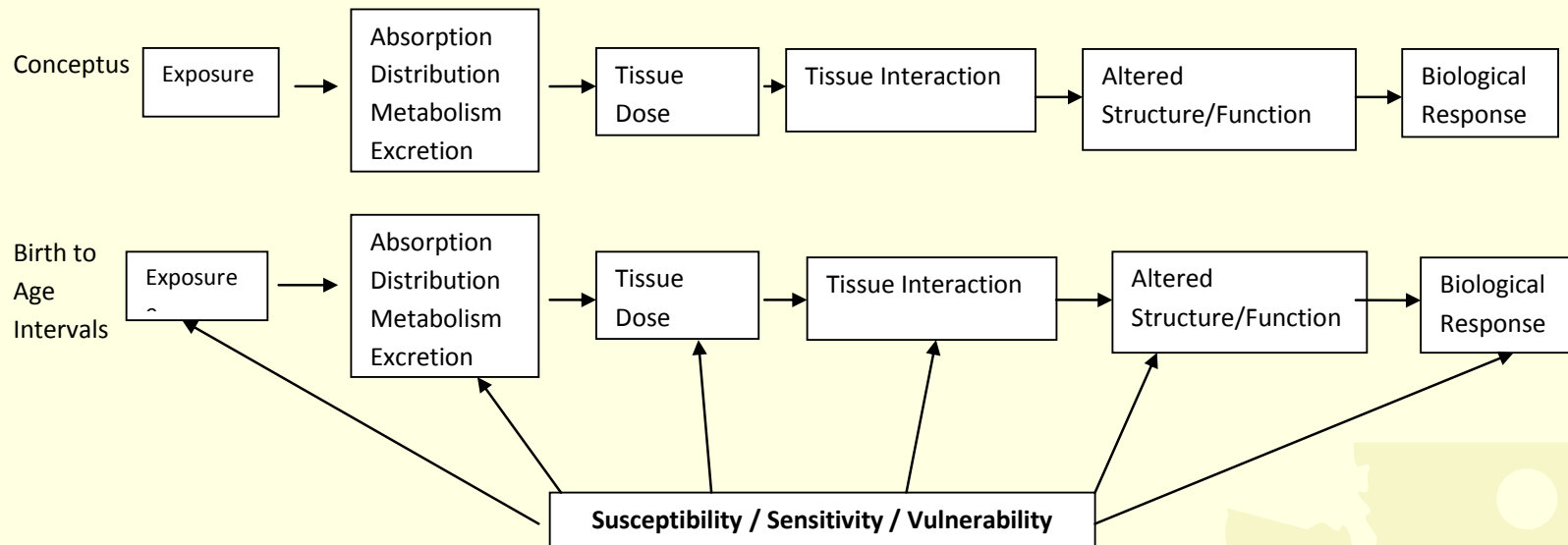


## Behavior & Physiology-Related Characteristics Considered in Deriving Recommended Set of Childhood Age Groups

Selected Age Groups	Characteristics Considered
Birth to < 1 Month	<p><u>Behavior-Related</u>: Time spent sleeping or sedentary; breast &amp; bottle feeding</p> <p><u>Physiology-Related</u>: Rapid growth and weight gain; increasing proportion of body fat; high skin permeability; high oxygen requirements (increased breathing rate); deficiencies in hepatic enzyme activity; immature immune system; more alkaline stomach; increases in extracellular fluid; renal function less than predicted by body surface area</p>
6 to < 12 Months	<p><u>Behavior-Related</u>: Food consumption expands; floor mobility increases (surface contact); children are increasingly likely to mouth nonfood items; children develop personal dust clouds</p> <p><u>Physiology-Related</u>: Rapid growth and weight gain; body fat increases begin to moderate; deficiencies in hepatic enzyme activity; immature immune system; rapid decrease in extracellular fluid; can begin predicting renal function by body surface area</p>
3 to < 6 Years	<p><u>Behavior-Related</u>: Continued increases in the occupancy of outdoor spaces</p> <p><u>Physiology-Related</u>: Entering a period of relatively stable weight gain and skeletal growth (as opposed to a period marked by growth spurts)</p>
11 to < 16 Years	<p><u>Behavior-Related</u>: Smoking may begin; increased rate of food consumption; increased independence (more time out of home); workplace exposures can begin</p> <p><u>Physiology-Related</u>: Rapid skeletal growth; rapid reproductive and endocrine system changes</p>
Adapted from Firestone et. al., 2007. Identifying Childhood Age Groups for Exposure Assessment and Monitoring. Risk Analysis, Vol. 27, No 3, page 705, Table IV. And EPA Summary Report of the Technical Workshop on Issues Associated with Considering Developmental Changes in Behavior and Anatomy when Assessing Exposure to Children, 2000, EPA/630/R-00/005	

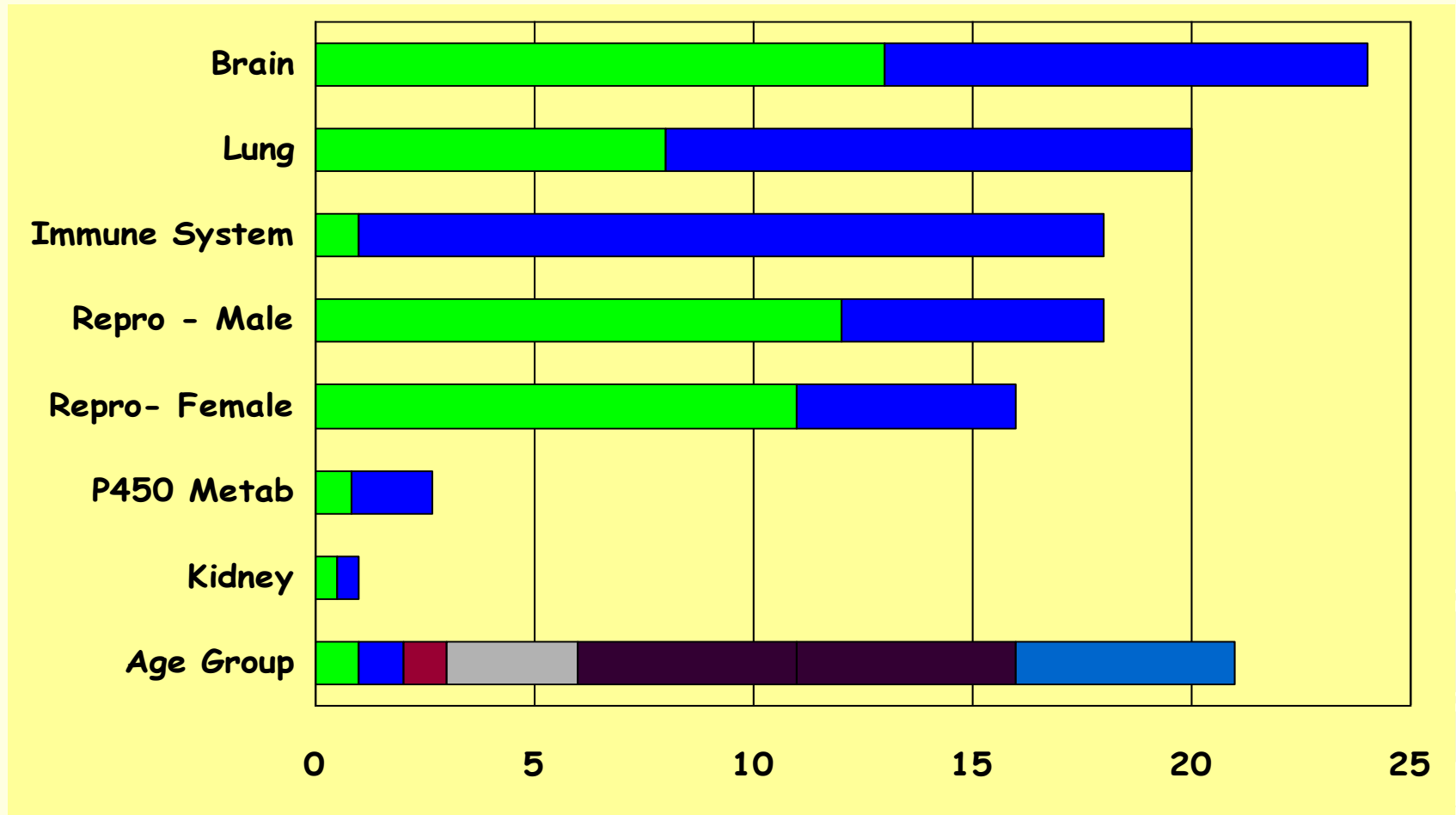
# Life Stage Differences in Dose-Response

Exposure Assessment	Dose - Response	
Exposure Characteristics	Toxicokinetics	Toxicodynamics



Adapted from U.S. EPA: Framework for Assessing Health Risks of Environmental Exposures to Children

# General Timelines for Organ System Developmental Stages



# Susceptibility/Sensitivity/Vulnerability

- **Susceptibility**: Increased likelihood of an adverse effect or exposure, often discussed in terms of relationship to a factor, that can be used to describe a human subpopulation, (e.g., lifestage, demographic feature, or genetic characteristic). “...capacity characterized by biological (intrinsic) factors that can modify the effect of a specific exposure, leading to high health risk at a given relevant exposure level.”
- **Sensitivity**: “..capacity for higher risk due to the combined effect of susceptibility (biological factors) and differences in exposure.”
- **Vulnerability**: “..incorporates the concepts of susceptibility and sensitivity, as well as additional factors that include social and cultural parameters (e.g., socio-economic status and location of residence) that can contribute to an increased health risk.”

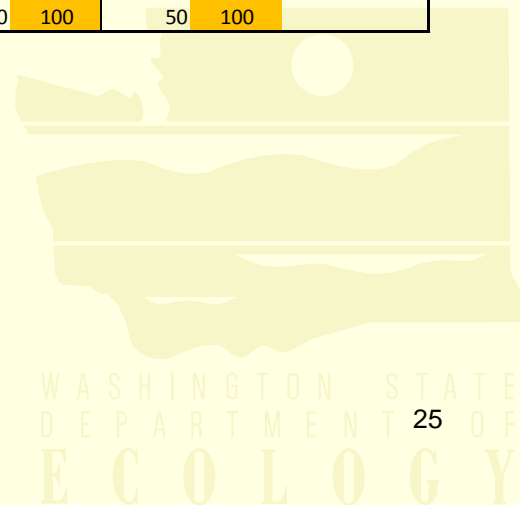
# Martha's table

Comparing Early-Life Exposure Cleanup Levels for B[a]P With Other Soil Values			
SOIL VALUES	Exposure Pathways	Exposure Duration	Concentration (mg/kg,ppm)
<b>Current Rule Cleanup Levels</b>			
Method A, unrestricted land use		6 years	0.1
Method A, industrial land use		20 years	2
Method B	ingestion	6 years	0.14
Modified Method B	Ingestion + Dermal	6 years	0.104
Method C	Ingestion	20 years	18
<b>Accounting For Early-Life (Children's Susceptibility)</b>			
Using EPA & Cal-EPA Methodology	Ingestion	30 years	n/a
Using EPA & Cal-EPA Methodology	Ingestion + Dermal	30 years	0.017
Using EPA & Cal-EPA Methodology	Ingestion + Dermal + Inhalation	30 years	0.017
<b>MTCA Cleanup Levels From Other Pathways</b>			
Soil concentration protective of groundwater	3-Phase Soil Leaching Model	n/a	0.43
Soil concentration protective of indoor air		n/a	???
TEE (simplified, unrestricted)	Terrestrial Ecological Eval.	n/a	30
Background concentration (national data)	Upper 95% B[a]P	n/a	3.3



# Example of Early-Life Stage Adjustment for Incidental Soil **Ingestion**

1	Early Life Exposure Age Adjustments for <b>Soil Ingestion</b> from exposure to carcinogen, $IFS_{ele-adj}$ , mg-year/kg-day													
	$IFS_{ele-adj} =$	$ED_{0-2} * SIRc * 10$	plus	$ED_{2-6} * SIRc * 3$	plus	$ED_{6-16} * SIRa * 3$	plus	$ED_{16-30} * SIRa * 1$						
		BWc		BWc		BWa		BWa						
Early Life Exposure Age Adjustment Factors for Carcinogens, Soil Ingestion Pathway														
Parameter	Parameter Definition				Default Exposure Parameters For Early Life Exposure									
					Age Groupings									
					< 2 years		2 to < 6 Years		6 to < 16 years		Adult			
					Default	Alternative	Default		Default	Alternative	Default	Alternative		
ADAF		Age-Dependent Adjustment Facotr, Unitless			10		3		3		1			
ED		Exposure Duration, years			2		4		10		14		adds up to 30	
BW		Body weight, kg			16	≈ 10	16		70	≈ 45	70			
SIR		Soil Ingestion Rate, mg/day			200		200		50	100	50	100		



# Estimated Total Costs of Pediatric Disease of Environmental Origin

Disease	Best Cost Estimate (Billions \$)	Low Cost Estimate (Billions \$)	High Cost Estimate (Billions \$)
Lead Poisoning	43.4	43.4	43.4
Asthma	2.0	0.7	2.3
Cancer	0.3	0.2	0.7
Neurobehavioral Disorders	9.2	4.6	18.4
Total	54.9	48.8	64.8

- The Environmental Protection Agency has published updated procedures for inhalation risk assessments.
  - Does the new EPA guidance provide a solid scientific foundation for evaluating revisions to the MTCA rule? [In other words, are these procedures consistent with current scientific information?]
  - Is there additional scientific information and regulatory guidance on this issue that Ecology should consider during the rulemaking process?